

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**

**PEOPLE FOR THE ETHICAL
TREATMENT OF ANIMALS, INC.,**

Plaintiff,

v.

DR. LAWRENCE A. TABAK, et al.,

Defendant.

Civ. No. MJM-21-2413

* * * * *

MEMORANDUM ORDER

Plaintiff People for the Ethical Treatment of Animals, Inc. (“Plaintiff” or “PETA”) filed this civil action under the Administrative Procedure Act (“APA”) to challenge final agency actions by the National Institutes of Health (“NIH” or the “Agency”), Department of Health and Human Services (“HHS”), and their head officers (collectively, “Defendants”). ECF No. 1 (Complaint). Specifically, Plaintiff alleges that Defendants violated the APA in 2020 and 2021 by awarding biomedical research grants to five institutions to conduct experiments involving rodents to study sepsis in humans. *See id.* Defendants have answered the Complaint, ECF No. 87, and an administrative record is on file, ECF Nos. 111 & 112.

Currently pending is Plaintiff’s Motion for Admission of Extra-Record Evidence. ECF No. 141. Defendants filed a response in opposition to the motion, ECF No. 144, and Plaintiff filed a reply, ECF No. 147. No hearing is necessary to resolve the motion. *See* Loc. R. 105.6 (D. Md. 2023). For the reasons set forth below, the motion shall be granted in part and denied in part.

I. LEGAL STANDARD

Under the APA, the court must “hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” *Appalachian Voices v. U.S. Dep’t of Interior*, 25 F.4th 259, 268 (4th Cir. 2022) (quoting 5 U.S.C. § 706(2)(A)). “To comply with the APA, the agency must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made.” *Roe v. Dep’t of Def.*, 947 F.3d 207, 220 (4th Cir. 2020), *as amended* (Jan. 14, 2020) (quoting *Sierra Club v. Dep’t of Interior*, 899 F.3d 260, 293 (4th Cir. 2018)) (internal quotation marks omitted). “Agency action is arbitrary and capricious ‘if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.’” *Appalachian Voices*, 25 F.4th at 269 (quoting *Motor Vehicle Mfrs. Ass’n of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). Under this standard, judicial review “is highly deferential, with a presumption in favor of finding the agency action valid.” *Id.* (quoting *Ohio Valley Env’t Coal. v. Aracoma Coal Co.*, 556 F.3d 177, 192 (4th Cir. 2009)). The court cannot “substitute its judgment for that of the agency.” *Motor Vehicle Mfrs. Ass’n*, 463 U.S. at 43. “Nevertheless, [the court] must conduct a ‘searching and careful’ review to determine whether the agency’s decision” violated the APA. *Appalachian Voices*, 25 F.4th at 269.

“Judicial review of administrative action is generally confined to the administrative record.” *Fort Sumter Tours, Inc. v. Babbitt*, 66 F.3d 1324, 1335 (4th Cir. 1995). *See also Sanitary*

Bd. of City of Charleston, W. Virginia v. Wheeler, 918 F.3d 324, 334–35 (4th Cir. 2019) (“[T]he focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court.”) (quoting *Camp v. Pitts*, 411 U.S. 138, 142 (1973)); *Nat’l Fed’n of the Blind v. U.S. Abilityone Comm’n*, 421 F. Supp. 3d 102, 145 (D. Md. 2019) (“[A] court is ordinarily limited to evaluating the agency’s contemporaneous explanation in light of the existing administrative record[.]”) (quoting *Dep’t of Com. v. New York*, 588 U.S. 752, 780 (2019)). Courts recognize “a presumption that the record compiled by the agency is the record on which it rested its decision[.]” and “will ordinarily assume that the administrative record is complete and exclusive for purposes of judicial review.” *Sanitary Bd. of City of Charleston*, 918 F.3d at 334.

“However, . . . there may be circumstances to justify expanding the record or permitting discovery.” *Fort Sumter Tours*, 66 F.3d at 1336 (citation omitted). The “limited circumstances” in which a court may consider extra-record evidence include cases where the evidence “(1) explains technical information or agency action not adequately explained in record; (2) shows an agency failed to consider relevant evidence; or (3) shows an agency, in bad faith, failed to include information it considered in the record.” *Sierra Club v. Nat’l Marine Fisheries Serv.*, 711 F. Supp. 3d 522, 540–41 (D. Md. 2024) (quoting *Hodges v. Abraham*, 253 F. Supp. 2d 846, 855 (D.S.C. 2002), *aff’d*, 300 F.3d 432 (4th Cir. 2002)). *See also Roe*, 947 F.3d at 221 (holding that, in cases “where ‘there [is] such failure to explain administrative action as to frustrate effective judicial review[.]’” courts may consider affidavits outside the agency record that “provide ‘background information or evidence of whether all relevant factors were examined by an agency,’” or they “merely” explain the agency record) (citations omitted); *Save Our Sound OBX, Inc. v. N. Carolina Dep’t of Transportation*, 914 F.3d 213, 226–27 (4th Cir. 2019) (“We may supplement the record

as presented by the agency if the ‘bare record’ does not reveal the agency’s reasoning or if it appears that the agency acted in bad faith.”) (quoting *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 420 (1971)). “A party challenging an agency bears a special burden of demonstrating that the court should reach beyond the record, either to examine information that should have been before the agency but was not, or to introduce extra-record evidence that the agency actually relied on that was omitted from the administrative record.” *Sanitary Bd. of City of Charleston*, 918 F.3d at 334. “Whether to admit extra-record evidence pursuant to an exception is a matter within the Court’s discretion.” *Sierra Club*, 711 F. Supp. 3d at 541 (citation omitted).

II. DISCUSSION

Plaintiff requests admission of the following materials outside the administrative record:

(1) the Declaration of Dr. Nathan Dean Nielsen, M.D., M.Sc., and several exhibits attached to this declaration, ECF No. 141-3 (“Nielsen Decl.”); (2) five exhibits attached to the Declaration of Elisabeth Custalow, Esq., ECF No. 141-4 (“Custalow Decl.”).

A. Dr. Nielsen’s Declaration and Exhibits

Dr. Nielsen is a physician, medical researcher, and professor with substantial education, training, and experience in sepsis and related subjects. Plaintiff proffers several reasons for offering Dr. Nielsen’s declaration, to include providing technical information Plaintiff deems necessary to explain portions of the administrative record and place them in context, explaining relevant standards of the peer review process and scientific method, and interpreting the grant applications and evaluations at issue in this litigation.

Having reviewed Dr. Nielsen’s declaration and its attachments, and relevant portions of the administrative record, the Court finds that effective judicial review of the agency actions challenged in this case requires consideration of at least some of the information contained within

and attached to Dr. Nielsen's declaration, while other parts of Dr. Nielsen's declaration are not necessary for effective judicial review. To be clear, the Court does not find that Defendants have acted in bad faith in excluding relevant information from the administrative record. But the Court finds portions of Dr. Nielsen's declaration and some of its attachments necessary to explain technical information that is not adequately explained in the record and to permit a showing by Plaintiff that the Agency failed to consider relevant evidence in taking the challenged actions.

Dr. Nielsen's declaration is organized into eleven sections, with clearly identified headers. Sections I and II summarize Dr. Nielsen's education, experience, and qualifications specific to sepsis research, which is also listed in curriculum vitae ("CV") attached as Exhibit 1 to the declaration. Section III describes the information Dr. Nielsen considered in producing analyses presented in later sections of the declaration, which is also listed in Exhibit 2. Exhibit 3 is Dr. Nielsen's acknowledgment of the Court's Confidentiality Order in this case. Although the foregoing sections and materials do not specifically concern the agency actions challenged in this case, the Court finds it appropriate to admit these sections to place other admissible portions of the declaration on a proper foundation. Sections I through III and Exhibits 1 through 3 will be admitted.

Section IV provides technical definitions and background information concerning sepsis research. Paragraphs 102 through 118 contains definitions of scientific and medical terms used in the administrative record and background information on sepsis. The Court finds Dr. Nielsen to be qualified to provide this explanatory information, considering his education, training, and experience, as reflected in Sections I and II and his CV. Given the scientific and technical complexity of the subject matter, the information contained in Paragraphs 102 through 118 is useful in providing objective explanations of terms and concepts used and referenced in the

administrative record, and the Court finds this information necessary for effective judicial review. *See Sierra Club*, 711 F. Supp. 3d at 543–44 (finding portion of expert declaration that defines key terms used in a scientific study and explains its complex methodology to be admissible “[i]n light of the complexity of the subject matter, the opacity of the relevant vocabulary and methods, and the absence of a court-appointed expert”). Paragraphs 102 through 118 of the Nielsen Declaration will be admitted.

However, the remainder of Section IV and Section V will not be admitted. Paragraphs 119 through 123 of Section IV list facts and principles about animal-based sepsis experiments and the translatability to sepsis in humans, which Dr. Nielsen claims are “generally understood and accepted within the scientific community.” Nielsen Decl. ¶¶ 119–23. Similarly, Section V purports to “explain the scientific community’s consideration of the lack of translatability of animal-based sepsis research.” *Id.* ¶¶ 12, 124–41. In Section V, Dr. Nielsen discusses two peer-reviewed publications describing differences between sepsis in humans and that in other animals, and discusses the National Advisory General Medical Sciences Council (“NAGMSC”) Working Group on Sepsis Final Report 2019. These three documents are also attached to Dr. Nielsen’s declaration as Exhibits 4, 5, and 6, respectively. Dr. Nielsen explains that the two peer-reviewed publications discussed in Section V and attached to the declaration are but two of “the most influential” of “[a]t least eighteen peer-reviewed publications over the past twenty-one years [that] have described how sepsis in humans fundamentally differs from sepsis in other animals.” *Id.* ¶¶ 125–26.

The Court finds that Paragraphs 119 through 123 of Section IV and Section V (Paragraphs 124 through 141) of Dr. Nielsen’s declaration are not necessary or appropriate for admission. Paragraphs 119 through 141 are not needed to explain technical concepts, and the Court does not

require one expert's opinion about how the relevant scientific community has assessed the translatability of animal-based sepsis research to sepsis in humans. Nielsen Decl. ¶ 12. Plaintiff fails satisfy its "special burden" of demonstrating that Dr. Nielsen's assessment of this topic "should have been before the agency but was not[.]" *Sanitary Bd. of City of Charleston*, 918 F.3d at 334.

As Defendants emphasize, Dr. Nielsen's opinions about the views prevailing within the scientific community are a far cry from the expert declaration Judge Boardman found to be admissible in *Sierra Club*. The *Sierra Club* plaintiffs offered this declaration, in part, to show that that the agency failed to consider an important implication of a specific scientific study the agency interpreted and relied upon in drawing conclusions challenged in that case. *Sierra Club*, 711 F. Supp. 3d at 544. Given the methodological complexity of the study, the court found that the declaration would aid its assessment of "whether the government failed to consider something it should have." *Id.* The court found support for its conclusion among several cases, including *Dynacorp International, LLC v. United States*, 125 Fed. Cl. 1 (Fed. Cl. 2016). In *Dynacorp*, the Court of Federal Claims admitted an extra-record expert report offered to explain "the nature of the proprietary data" disclosed by the agency and how its disclosure affected the plaintiff, which the plaintiff contended was "necessary for meaningful judicial review" of the reasonableness of challenged agency decisions. 125 Fed. Cl. at 3. Importantly, like the expert declaration admitted in *Sierra Club*, the report at issue in *Dynacorp* "d[id] not introduce extra-record facts, but instead include[d] calculations and explanations based on data in the contemporaneous record to aid the Court in better understanding the record." *Id.*, quoted in *Sierra Club*, 711 F. Supp. 3d at 542.

Here, in contrast, Plaintiff offers a series of facts one expert considers to be "generally understood and accepted within the scientific community" and the expert's views on peer-

reviewed studies that have been “most influential” in the community. Nielsen Decl. ¶¶ 119–23, 126. The only conceivable use this extra-record information may hold for the Court is “to judge the wisdom of the agency’s action[,]” which is “never permitted.” *San Luis & Delta-Mendota Water Auth. v. Locke*, 776 F.3d 971, 993 (9th Cir. 2014) (citing *Asarco, Inc. v. U.S. Env’t Prot. Agency*, 616 F.2d 1153, 1160 (9th Cir. 1980)); *see also Motor Vehicle Mfrs. Ass’n*, 463 U.S. at 43 (“The scope of review under the ‘arbitrary and capricious’ standard is narrow and a court is not to substitute its judgment for that of the agency.”). Under the APA, a court is to “review scientific judgments of the agency ‘not as the chemist, biologist, or statistician that we are qualified neither by training nor experience to be, but as a reviewing court exercising our narrowly defined duty of holding agencies to certain minimal standards of rationality.’” *Troy Corp. v. Browner*, 120 F.3d 277, 283 (D.C. Cir. 1997) (quoting *Ethyl Corp. v. EPA*, 541 F.2d 1, 36 (D.C. Cir. 1976), *cert. denied*, 426 U.S. 941 (1976)). One expert’s extra-record summation about what views prevail in the relevant scientific community has no legitimate role to play or purpose to serve in this Court’s review of the challenged agency actions.¹ The Court notes, however, that the Seok Study (Exhibit 4),² one of the peer-reviewed publications discussed in Section V, and the NAGMSC Working

¹ There is an apparent lack of unanimity within the relevant scientific community on at least some of the issues discussed in Paragraphs 119 through 141 of the Nielsen Declaration. Dr. Nielsen cites a peer-reviewed study by Junhee Seok, et al. as “[a]mong the most influential” of peer-reviewed studies over the past two decades concerning “how sepsis in humans fundamentally differs from sepsis in other animals[,]” attaching a copy of that study as Exhibit 4 to the declaration. Nielsen Decl. ¶¶ 125–26, Ex. 4; *see also* Seok, et al., *Genomic responses in mouse models poorly mimic human inflammatory diseases*, 110(9) Proc. Nat’l Acad. Sci. 3507, 3507–12 (2013) (“Seok Study”). But, as Defendants point out, a subsequent study by Keizo Takao, et al. disputes and challenges some of the conclusions drawn from the Seok Study. *See* Takao, et al., *Genomic responses in mouse models greatly mimic human inflammatory diseases*, 112(4) Proc. Nat’l Acad. Sci. 1167–72, *corrected*, 112(10) Proc. Nat’l Acad. Sci. E1163 (2015). The Court has no role in resolving these disputes or deciding which views should or should not have been accepted within the Agency. “When specialists express conflicting views, an agency must have discretion to rely on the reasonable opinions of its own qualified experts even if, as an original matter, a court might find contrary views more persuasive.” *Marsh v. Oregon Nat. Res. Council*, 490 U.S. 360, 378 (1989).

² Seok, et al., *Genomic responses in mouse models poorly mimic human inflammatory diseases*, 110(9) Proc. Nat’l Acad. Sci. 3507, 3507–12 (2013).

Group on Sepsis Final Report 2019 (Exhibit 6) were apparently referenced in connection with the challenged grants, as reflected in the administrative record. Upon review of these materials and relevant portions of the administrative record, the Court finds the references to these materials in the record to justify considering the materials themselves during the merits phase of this case. These materials may provide information considered in connection with the challenged grants but “not adequately explained in record” and may be necessary to permit a showing by Plaintiff that the Agency “failed to consider relevant evidence.” *Sierra Club*, 711 F. Supp. 3d at 540–41 (quoting *Hodges*, 253 F. Supp. 2d at 855). Accordingly, Exhibits 4 and 6 to Dr. Nielsen’s declaration will be admitted,³ but Exhibit 5 will not.

Sections VI through X of Dr. Nielsen’s declaration purports to “explain the peer review process that occurred with respect to” each of the grants challenged in this case, and Section XI offers some concluding commentary about the peer review processes. Nielsen Decl. ¶¶ 13–17, 142–200. The Court does not find these sections of the declaration necessary to explain technical concepts to the Court or the process surrounding the grant applications and approvals. And, again, Plaintiff fails satisfy its burden of justifying admission of Dr. Nielsen’s opinions and comments about these processes. *See Sanitary Bd. of City of Charleston*, 918 F.3d at 334. Sections VI through XI will not be admitted.

B. Exhibits to Ms. Custalow’s Declaration

Plaintiff also seeks admission of several documents that PETA sent to the NIH in October 2019, which it contends reflect factors the Agency should have considered but failed to during the

³ The Court does not consider Dr. Nielsen’s comments about these materials in Section V of his declaration to offer necessary assistance to the Court’s consideration of them.

challenged agency actions. These documents are attached as exhibits to the declaration of Elisabeth Custalow, PETA's Deputy General Counsel.

Exhibit 2 to the Custalow Declaration is the Seok Study, and Exhibit 3 is the 2019 Final Report of the NAGMSC Working Group on Sepsis. These documents, which were also attached to Dr. Nielsen's declaration, will be admitted, for reasons explained in Part II.A *supra*.

Exhibit 1 to the Custalow Declaration is a blog post authored by then-NIH Director Francis Collins containing commentary by Dr. Collins on the Seok Study. As noted, the Seok Study itself will be admitted because it is referenced in connection with the challenged agency actions. However, Plaintiff presents no evidence that Dr. Collins's blog post was considered and makes no showing that it should have been considered but was not. The fact that the blog post was authored by the NIH Director does not by itself make it a factor the Agency was required to consider in evaluating the challenged grant applications. Plaintiff fails to show how the blog post presents any "important aspect of the problem" not presented in the Seok Study it discusses. The Seok Study itself (Exhibit 2) will be admitted, but Dr. Collins's blog post about the study (Exhibit 1) will not.

Exhibit 4 to the Custalow Declaration is a notice issued by the National Institute of General Medical Sciences ("NIGMS") to applicants for NIGMS grants. The notice discusses the work and recommendations of the NAGMSC Working Group on Sepsis and lists as an area "of low priority" "[s]tudies using rodent models of sepsis" Custalow Decl., Ex. 4. Again, Plaintiff fails to demonstrate that this notice, addressed to grant applicants to NIGMS, was considered or should have been considered within the Agency regarding the challenged agency actions. NIGMS is a component of NIH separate from those responsible for the grants at issue in this case. As Defendants explain, each NIH component has its own statutory purposes and authorities, and its own research agendas. Plaintiff fails to show how the NIGMS notice presents any "important

aspect of the problem” not presented in the NAGMSC Working Group report it references. The working group report (Exhibit 3) will be admitted, but the NIGMS notice (Exhibit 4) will not.

Exhibit 5 to the Custalow Declaration is described as “[a] document that NIH provides to grant applicants to provide guidance on applying for funding[.]” Custalow Decl. ¶ 7.e. Specifically, the document is a sample Notice of Funding Opportunity that includes annotations, or “tips,” offered as guidance to NIH grant applicants. Plaintiff presents this document to assist the Court in understanding standards generally observed by NIH in connection with its evaluation of grant applications. Upon review of the document, the Court finds it to provide useful context for the grant applications at issue in this case and the Funding Opportunity Announcements for those applications, which are in the administrative record. Exhibit 5 is a brief 25-page document, and the relevant “tips” are but a small portion of the document. In the exercise of its discretion, and given the explanatory value it finds in the annotations, the Court will admit Exhibit 5.

III. CONCLUSION

For the foregoing reasons, it is by the United States District Court for the District of Maryland, hereby ORDERED that Plaintiff’s Motion for Admission of Extra-Record Evidence is granted in part and denied in part. The following extra-record evidence will be admitted: Paragraphs 1 through 118 of the Nielsen Declaration; Exhibits 1, 2, 3, 4 and 6 to the Nielsen Declaration; and Exhibits 2, 3, and 5 to the Custalow Declaration.

It is so ORDERED this 22nd day of September, 2025.

/S/
Matthew J. Maddox
United States District Judge